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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,735	02/04/2004	Takashi Tokuyama	F-8021	4827
28107 7590 11/18/2008 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168				
EXAMINER WINSTON, RANDALL O				
ART UNIT		PAPER NUMBER		
1655				
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11/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/771,735

**Applicant(s)**

TOKUYAMA ET AL.

**Examiner**

Randall Winston

**Art Unit**

1655

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 29-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 0908
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Acknowledgement is made of receipt an entry of the amendment filed on 06/02/2008.

Applicant's amendment has overcome Examiner's 112, first paragraph, rejection.

Examiner acknowledges that claims 27-28 have been withdrawn from consideration and new claims 30-42 have been added.

Claims 1-26 and 29-42 have been examined on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 25-26 and 34 are rejected under 35 USC 102(b) as being anticipated by Tanaka et al. (US 5128375) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a method of treating the skin by applying to the skin a composition comprising ethanolamine.

Tanaka anticipates the claimed invention because Tanaka teaches a method of treating the skin by applying to the skin a composition comprising ethanolamine (see, e.g. entire patent including abstract). Therefore, the reference is deemed to anticipate the claimed invention.

Applicant's argument has been carefully considered but it is not deemed persuasive. Applicant argues Tanaka et al. discloses a keloid treating agent and fails to disclose or suggest the above-identified mechanism of moisture retention ability of the present invention.

Although Applicant argues Tanaka et al. discloses a keloid treating agent and fails to disclose or suggest the above-identified mechanism of moisture retention ability of the present invention, Applicant argument is not found persuasive because since both Tanaka's composition comprising of the same active ingredient as the claimed invention's composition comprising of the same active ingredient are applied to the skin, both the Tanaka's composition and the claimed invention's composition would inherently have the same claimed functional effect (i.e. the functional effect of improving moisture retention and/or for another claimed purpose) when applied to the skin.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 and 29-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al. (US 5,753,214) in view of Tanaka et al. (US 5128375) and Pola Chem Ind Inc (Derwent Acc-No 1995-175320 and/or JP 07097312A, see

abstract) as evidenced by Pearson et al. (6,951,658) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a method of treating the skin by applying to the skin a composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent).

Yoshioka teaches a composition comprising L-arginine (please note, as evidenced by Pearson et al. L-arginine is inherently found in rice, thus, it is considered a "rice preparation"), and an antiphlogistic agent (i.e. anti-inflammatory agent) used within a cosmetic composition to be applied to a subject's skin to treat skin disorders (see, e.g. entire patent including the abstract, column 9 lines 1-35, column 17 lines 23-34).

Yoshioka et al. do not expressly teach ethanolamine and a moisture retention agent of 1,3-butyleneglycol included within its cosmetic composition to be applied to a subject's skin to treat skin disorders.

Tanaka beneficially teaches ethanolamine contained within a cosmetic composition to be applied to a subject's skin to treat skin disorders (see, e.g. claim 15).

Pola Chem Ind Inc beneficially teaches 1,3-butyleneglycol contained within a cosmetic composition to be applied to a subject's skin to treat skin disorders (see, e.g. column 4 lines 44-53).

One of ordinary skill in the art of creating the claimed invention would have been motivated to modify Yoshioka's cosmetic composition's teachings to include the other claimed active ingredients as taught by Tanaka and Pola Chem Ind Inc. within

Yoshioka's cosmetic compositions because the above combined references as a whole would create the claimed method of treating the skin by applying to the skin a composition comprising L-arginine, ethanolamine, 1,3-buteneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent) to treat skin disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose". Moreover, the adjustment of other conventional working conditions (e.g. determining suitable amounts/ranges of each active ingredient within the claimed composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note that the patentability of a product (i.e. L-arginine originated in a rice preparation and/or plant preparation (e.g. especially see claim 40)) does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues that the present invention is not obvious over Yoshioka, Tanaka and Pola Chem Ind Inc, and therefore the claims are patentable over the cited prior art and notice to this is respectfully requested.

Although Applicant argues that the present invention is not obvious over Yoshioka, Tanaka and Pola Chem Ind Inc, and therefore the claims are patentable over the cited prior art and notice to this is respectfully requested, Applicant argument is not found persuasive because as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose. Therefore, one of ordinary skill in the art of creating the claimed invention would have been motivated to modify Yoshioka's cosmetic composition's teachings to include the other claimed active ingredients as taught by Tanaka and Pola Chem Ind Inc. within Yoshioka's cosmetic compositions because the above combined references as a whole would create the claimed method of treating the skin by applying to the skin a composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent) to treat skin disorders. Moreover, when the combined cited reference as a whole created composition comprising of the same active ingredients as the claimed invention's composition comprising of the same active ingredients are applied to the skin, both the combined cited reference as a whole created composition and the claimed invention's composition would intrinsically have the same claimed functional effect (i.e. the functional effect of improving moisture

retention and/or treating atopic dermatitis and/or inflammation and/or for another claimed purpose) when applied to the skin.

Moreover, Applicant argues the Office Action has not demonstrated that any of compounds and/or L-arginine originated in a rice preparation.

Although Applicant argues the Office Action has not demonstrated that any of compounds and/or L-arginine originated in a rice preparation, Applicant argument is not found persuasive because the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Lastly, Applicant argues that Applicant wish to point out that the present invention demonstrates synergistic results because the use of both ethanolamine and L-arginine provides synergistic results as is clear from examples 4-6 and Figure 21 of the present specification.

Although Applicant argues Applicant argues that Applicant wish to point out that the present invention demonstrates synergistic results because the use of both ethanolamine and L-arginine provides synergistic results as is clear from examples 4-6 and Figure 21 of the present specification, Applicant argument is not found persuasive because the specification does not demonstrate that a composition with all the claimed ingredients functions better than a composition with just one of the claimed ingredients (see, e.g. MPEP 716.02)). Therefore, applicant's specification does not support unexpected results. Furthermore, it appears to examiner that applicant also has not



claimed any specific effective amounts and/or ranges of active ingredients within its claimed composition of claims 1-26, 29-35 and 40-42 to determine whether applicants' claimed composition invention demonstrates unexpected results and synergism. What specific effective amounts and/or ranges of active ingredients within applicants' claimed composition of claims 1-26, 29-35 and 40-42 (i.e. especially in independent claim 1) produce unexpected results and synergism?

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655